REMARKS

Applicants respectfully request entry of the above amendments and reconsideration of the following arguments pursuant to 37 C.F.R. § 1.111.

1. Status of the Claims

Claims 1-25 stand pending. Claims 6-7 and 24-25 stand withdrawn. Claims 1-5 and 8-23 stand rejected.

Upon entry of the present amendment, claims 2-3, 6-7, 14-15, 19-20, and 24-25 stand canceled. Applicants amend claims 1 and 16-18 to more distinctly recite the claimed subject matter. Applicants introduce new claims 26-30. Support for the amendments can be found at least in the originally presented claims and at least in the Specification at:

Claim	Exemplary Support
1	original claims 1, 3, and 14-15; first full para., p. 15 and first full para., p. 16 of the Specification
16	original claims 14 and 16
17	original claims 14 and 17
18	original claims 14 and 18
26	original claims 1, 3, and 14; first full para., p. 15, first full para., p. 16, and first full para., p. 30 of the Specification
27	original claims 1 and 15; first full para., p. 16 of the Specification
28	original claims1 and 17
29	original claims 1 and 19
30	original claims 1 and 20

Accordingly, Applicants do not believe that any prohibited new matter is being introduced by the entry of the above amendments.

The claims have been amended without prejudice to, or disclaimer of, the canceled subject matter. Applicants reserve the right to file a continuation or divisional application on any subject matter canceled by way of amendment.

2. Acknowledgement of Receipt of Certified Priority Documents

Applicants appreciate the Office's acknowledgement that the certified priority documents have been received.

3. Acknowledgement of Information Disclosure Statements

Applicants appreciate the Office's acknowledgement of the Information Disclosure Statements (IDSs) filed June 2, 2006; October 11, 2006; and January 3, 2007.

Applicants respectfully request the Office's acknowledgement of the IDSs filed December 9, 2009 and March 22, 2010 with the next communication.

4. Restriction / Election Requirement

The Office made the prior Restriction Requirement final. Office action, page 2. Claims 24-25 are allegedly drawn to a nonelected invention and withdrawn from further consideration. *Id.* The Office made the prior Species Election final. *Id.*, at 3. Claims 6-7 are allegedly drawn to a nonelected species of the phospholipid and withdrawn from further consideration. *Id.*

The Office is respectfully reminded that Applicants reserve the right to file a Petition under 37 C.F.R. § 1.144 on the Office's position regarding restriction and/or species election in this matter.

5. Interview Summary

Applications appreciate the in-person interview conducted on March 8, 2010 between the Examiners and Applicants' representatives. During the interview, proposed amendments were compared with the rejection of record. The Office agreed that proposed amendments appear to overcome at least the § 102 rejections and § 112 rejections.

6. Rejection Under 35 U.S.C. § 112, First Paragraph (Written Description)

6.1. Claims 1-5 and 8-23

The Office rejects claims 1-5 and 8-23 under 35 U.S.C. § 112, first paragraph. The Office alleges that the term "LCPUFA supply compound" is merely indistinct, because the

Specification allegedly fails to provide a reasonably representative disclosure of useful LCPUFA supply compounds. Office Action, at 4-5.

Claims 1 and 26 as amended recite a "LCPUFA supply compound" as "at least one kind selected from the group consisting of free fatty acid, fatty acid alcohol ester, triglyceride, diglyceride, monoglyceride, glycoglycerolipid, sphingolipid, sugar ester, and carotenoid ester." As discussed in the interview, the amendment moots the rejection. Thus, the rejection of claims 1, 4-5, 8-13, 16-18, 21-23 is moot. The phrase is also included in new claims 26-30. Applicants respectfully request withdrawal of the rejection and allowance of the claims.

6.2. Claims 14-20

The Office rejects claims 14-20 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement, because the term "sugar derivative" is allegedly indistinct. Office Action, page 6.

Upon entry of the amendments, claims 14-20 no longer recite "sugar derivative." The rejection is thus moot. Applicants respectfully request withdrawal of the rejection and allowance of the claim.

7. Rejection Under 35 U.S.C. § 112, Second Paragraph

7.1. Claims 1-2, 4-5 and 8-23

The Office rejects claims 1-2, 4-5, and 8-23 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite, because of the phrase "wherein respective proportions of the first component and second component are determined according to the number of hydrolysable fatty acid bonds contained in the original phospholipid molecules." Office Action, page 7. The phrase is allegedly unclear regarding what is being compared. *Id.*

Amended claim 1 recites, *inter alia*, "***a total weight ratio*** of LCPUFA to be supplied from the LCPUFA or LCPUFA supply compound to the second component phospholipids." The claims are thus clear—the weight is being compared. Thus, the rejection is mooted as to claim 1, 4-5, 8-13, 16-18, and 21-23. The rejection is moot as to claims 2, 14-15, and 19-20 which stand canceled. Applicants respectfully request withdrawal of the rejection and allowance of the claims.

7.2. Claims 14-18

The Office rejects claims 14-18 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite, because the LCPUFA supply compound can include a fatty acid. Office Action, page 7. It is allegedly unclear how the supply compound contains a fatty acid, yet also will be hydrolyzed to form a fatty acid. *Id.*

Claims 14-15 stand canceled thereby mooting that aspect of the rejection. Claims 16-18 now depend directly or indirectly from claim 1, which recites that "the LCPUFA or LCPUFA supply compound is at least one kind selected from the group consisting of free fatty acid, fatty acid alcohol ester, triglyceride, diglyceride, monoglyceride, glycoglycerolipid, sphingolipid, sugar ester, and carotenoid ester." As discussed, the rejection is mooted. Applicants respectfully request withdrawal of the rejection and allowance of the claims.

7.3. Claims 2-3 and 18-20

The Office rejects claims 2-3 and 18-20 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for failure to specify the frame of reference used. Office Action, page 8.

The rejection is moot as to claims 2-3 and 19-20, which are canceled. Claim 18 is amended to depend form claim 1, which now recites *inter alia* "a total weight ratio of LCPUFA to be supplied from the LCPUFA or LCPUFA supply compound to the second component phospholipids." The rejection is thus moot and can be withdrawn.

7.4. Claims 2-3 and 17-20

The Office rejects claims 2-3 and 17-20 under 35 U.S.C. § 112, second paragraph, as indefinite, because there is allegedly insufficient antecedent basis for "suppliable fatty acids" and "suppliable LCPUFA." Office Action, page 8.

Amended claims 17-18 no longer recite "suppliable fatty acids" or "suppliable LCPUFA." Claims 2-3 and 19-20 are cancelled. The rejection is mooted and can be withdrawn.

7.5. Claims 14-20

The Office rejects claims 14-20 under 35 U.S.C. § 112, second paragraph, because the term "a sugar derivative" is unclear.

Claims 14-15 and 19-20 stand canceled and claims 18-18 stand amended to refer to amended claim 1, which no longer recites "sugar derivative." The rejection is thus moot, and can be withdrawn.

8. Rejection Under 35 U.S.C. § 102(b)

8.1. Claims 1-5, 8-17, 19, 21, and 23

The Office rejects claims 1-5, 8-17, 19, 21, and 23 under 35 U.S.C. § 102(b) as allegedly anticipated by **Ultimate Ginkgo** (*available at* http://www.edietstar.com/fact_sheet/ultimate_ginkgo.pdf, March 12, 2003 as of Internet Archive) ("Ultimate Ginkgo"). Ultimate Ginkgo allegedly discloses a composition formulated as a tablet that comprises 10 mg of docosahexaenoic acid (DHA) and 10 mg of phosphatidylserine derived from soybean. Office Action, page 10. The weight ratio of DHA and phosphatidylserine is 1:1. *Id.* The composition was allegedly for sale at the time Ultimate Ginkgo was generated. *Id.*

Applicants traverse the rejection to the extent it may be applied to the amended claims. Claim 1 as amended recites, *inter alia*, a composition comprising (1) a LCPUFA or LCPUFA supply compound and (2) phospholipids. The LCPUFA is recited as "at least one selected from the group consisting of: arachidonic acid, eicosadienoic acid, eicosatrienoic acid, eicosatetraenoic acid, eicosapentaenoic acid, docosadienoic acid, docosatrienoic acid, docosatetraenoic acid, docosapentaenoic acid, tetracosadienoic acid, tetracosatrienoic acid, tetracosatetraenoic acid, tetracosapentaenoic acid, and tetracosahexaenoic acid." The recited LCPUFA group does not include DHA. Accordingly, Ultimate Ginkgo does not disclose at least the claimed LCPUFA. For prior art to anticipate a claim, it must disclose each and every element of the claim explicitly or inherently. *See, e.g., In re Rijckaert*, 9 F.3d 1531, 1534, 28 U.S.P.Q.2d 1955, 1957 (Fed. Cir. 1993). As Ultimate Ginkgo does not disclose all claim elements, amended claim 1 is not anticipated. Dependent claims 4-5, 8-13, 16-17, 21, and 23 are

likewise not anticipated. The rejection is moot as to claims 2-3, 14-15, and 19, which stand canceled.

New claim 26 recites, *inter alia*, a weight ratio not less than 2 for LCPUFA to phospholipids. Ultimate Ginkgo does not disclose at least the recited ratio of claim 26. Ultimate Ginkgo therefore fails to teach all the limitations of claim 26.

In view of above arguments, Applicants respectfully request withdrawal of the rejection and allowance of the claims.

8.2. Claims 1-5 and 8-19

The Office rejects claims 1-5 and 8-19 under 35 U.S.C. § 102(b) as allegedly anticipated by **Hiratsuka** et al., U.S. Publish Patent Application No. 2003/0190392 A1 ("Hiratsuka"). Hiratsuka allegedly discloses a lipid mixture comprising 30.7% by weight neutrolipids and 69.3% by weight phospholipids, among which 9.5-12.4% by weight of the phospholipids are phosphatidylserine. Office Action, page 11. The lipid mixture also purportedly contains phosphatidylethanolamine. Hiratsuka allegedly discloses that DHA comprises 50.2-55.2% by weight of the phosphatidylserine, and arachidonic acid (AA) allegedly comprises about 0.8-2.2% of phosphatidylserine. *Id.* The Office alleges that (1) phosphatidylethanolamine is a phospholipid, and (2) DHA and arachidonic esters of phosphatidylserine read on the claimed LCPUFA supply compounds. *Id.*

Applicants traverse the rejection to the extent it may be applied to the amended claims. Claim 1 as amended recites, *inter alia*, that LCPUFA supply compound is selected from the group consisting of free fatty acid, fatty acid alcohol ester, triglyceride, diglyceride, monoglyceride, glycoglycerolipid, spingolipid, sugar ester, and carotenoid ester. Phospholipids, such as phosphatidylserine, are not enumerated as LCPUFA supply compounds. Hiratsuka does not disclose the claimed first component, a LCPUFA or a LCPUFA supply compound. Thus, Hiratsuka fails to teach all the elements of Claim 1 as amended, or any of its remaining dependent claims 4-5, 8-13, and 16-18. Hiratsuka thus fails to anticipate the claims. Claims 2-3, 14-15, and 19 stand canceled, mooting that aspect of the rejection.

New claim 26 recites, *inter alia*, that LCPUFA supply compound is selected from the group consisting of free fatty acid, fatty acid alcohol ester, triglyceride, diglyceride,

monoglyceride, glycoglycerolipid, spingolipid, sugar ester, and carotenoid ester. For the same reasons as above, Hiratsuka fails to disclose all the elements of claim 26, and cannot anticipate claim 26 or dependent claims 27-30.

In view of the above arguments, Applicants respectfully request withdrawal of the rejection and allowance of the claims.

9. Rejection of the Claims Under 35 U.S.C. § 103(a)

The Office rejects claims 18, 20, and 22 under 35 U.S.C. § 103(a) as allegedly obvious over Ultimate Ginkgo as applied to claims 1-5, 8-17, 19, 21, and 23, and further in view of **Stordy**, U.S. Patent No. 6,150,411 ("Stordy") and **Birch** et al., 42 DEV. MED. CHILD NEUROL. 14 (2000) ("Birch").

Ultimate Ginkgo allegedly teaches a combination of phosphatidylserine and DHA. Office Action, page 13. The Office admits that Ultimate Ginkgo does not teach AA. *Id.* Stordy allegedly teaches a composition 100 mg of DHA and optionally 100 mg of AA. *Id.* The composition is allegedly useful for treating dyslexia or inadequate night vision. Stordy allegedly suggests the incorporation of phospholipids. *Id.* The Office argues that a skilled artisan would have combined Stordy's composition with Ultimate Ginkgo's composition, because Stordy's composition is allegedly useful for treating dyslexia, and Ultimate Ginkgo's composition is useful for improving brain function. *Id.*, at 13-14. Birch is relied upon for its allegedly teaching that DHA supplementation might depress AA levels. *Id.*, at 14. The Office argues that a skilled artisan would have been motivated to administer AA to compensate the supplementation of DHA. *Id.*

Applicants traverse. To render a claim obvious, both the suggestion of the claimed invention and the expectation of success must be in the prior art, not from the disclosure of the claimed invention. *In re Dow Chem. Co.*, 837 F.2d 469, 5 U.S.P.Q.2d 1529 (Fed. Cir. 1988). "Obviousness requires a suggestion of ***all*** limitations in a claim." *CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1342, 68 U.S.P.Q.2d 1940, 1947 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985, 180 U.S.P.Q. 580, 583 (C.C.P.A. 1974) (emphasis added); *Examination Guidelines for Determining Obviousness under 35 U.S.C. 103 in View of the Supreme Court Decision in* KSR International Co. v. Teleflex Inc., 72 Fed. Reg. 57,528.

Amended claim 1 and its dependent claims (*e.g.*, claims 18 and 22) recite, *inter alia*, that (1) LCPUFA is "at least one selected from the group consisting of: arachidonic acid, eicosadienoic acid, eicosatrienoic acid, eicosatetraenoic acid, eicosapentaenoic acid, docosadienoic acid, docosatrienoic acid, docosatetraenoic acid, docosapentaenoic acid, tetracosadienoic acid, tetracosatrienoic acid, tetracosatetraenoic acid, tetracosapentaenoic acid, and tetracosahexaenoic acid," and (2) the claimed composition has a weight ratio of LCPUFA to phospholipids not less than 0.5. Applicants note that DHA is not among the group of fatty acids recited in amended claim 1. Ultimate Ginkgo does not teach other fatty acid(s) other than DHA. Neither Stordy nor Birch teach nor suggest combining a LCPUFA, such as arachidonic acid (AA) with phospholipids in the presently claimed weight ratio. Accordingly, the cited references, alone or when viewed in combination, do not teach or suggest all claim elements. The Office is further reminded that a skilled artisan must have had some apparent reasons to modify the known compositions in a way, *e.g.*, by varying the ratio of the components, that would result in the presently claimed compositions. *See Ex parte Whalen*, 89 U.S.P.Q.2d 1078, 1084 (Bd. Pat. App. & Int. 2008) (precedential). In the present case, the references, alone or viewed in combination, do not provide such a reason to reach the claimed weight ratio. Claims 18 and 22 are thus nonobvious. Claim 20 stands canceled, mooting the rejection.

New claims 26-30 recite, *inter alia*, a weight ratio not less than 2 for LCPUFA to phospholipids. At best, Ultimate Ginkgo may disclose a DHA to phosphatidylserine ratio of 1. Neither Stordy nor Birch teaches a ratio of LCPUFA to phospholipids. Accordingly, the cited references, alone or when viewed in combination, do not teach at least the ratio element of claim 26. There is also no apparent reason that a skilled artisan would have been directed to modify the ratio of Ultimate Ginkgo to reach the claimed composition. Claim 26 and its dependent claims 27-30 are thus nonobvious over the cited references.

In view of the above arguments, Applicants respectfully request withdraw of the rejection and allowance of the claims.

CONCLUSION

Should the Office have any questions or comments regarding Applicants' amendments or response, please contact Applicants' undersigned representative at (202) 842-8821. Furthermore, please direct all correspondence to the below-listed address.

In the event that the Office believes that there are fees outstanding in the above-referenced matter and for purposes of maintaining pendency of the application, the Office is authorized to charge the outstanding fees to Deposit Account No. 50-0573. The Office is likewise authorized to credit any overpayment to the same Deposit Account Number.

Respectfully Submitted,

Date: March 30, 2010 By: _____
Mercedes K. Meyer, Ph.D., Esq.
Registration No. 44,939

DRINKER BIDDLE & REATH LLP
Customer No. **55694**
1500 K Street, N.W., Suite 1100
Washington, D.C. 20005-1209
Tel. No.: (202) 842-8800
Fax No.: (202) 842-8465